

BRONKAID DUAL ACTION FORMULA- ephedrine sulfate and guaifenesin tablet, coated
Foundation Consumer Healthcare LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Bronkaid®
Dual Action Formula

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purpose</i>
Ephedrine sulfate 25 mg	Bronchodilator
Guaifenesin 400 mg	Expectorant

Uses

- for temporary relief of mild symptoms of intermittent asthma:
 - wheezing
 - tightness of chest
 - shortness of breath
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, drain bronchial tubes and make coughs more productive

Warnings

Asthma alert

Because asthma may be life threatening, see a doctor if you:

- are not better in 60 minutes
- get worse
- need more than 6 caplets in 24 hours
- use more than 4 caplets in 24 hours for more than 3 days a week
- have more than 2 asthma attacks in a week. These may be signs that your asthma is getting worse.

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- This product will not give you asthma relief as quickly as an inhaled bronchodilator.

Do not use

- unless a doctor said you have asthma
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- ever been hospitalized for asthma
- heart disease
- high blood pressure
- diabetes
- thyroid disease

- seizures
- narrow angle glaucoma
- a psychiatric or emotional condition
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a cough which is accompanied by excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are

- taking prescription drugs for asthma, obesity, weight control, depression, or psychiatric or emotional conditions
- taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as for allergy, cough-cold, or pain)

When using this product

- **your blood pressure or heart rate may go up. This could increase your risk of heart attack or stroke, which may cause death.**
- **your risk of heart attack or stroke increases if you:**
 - **have a history of high blood pressure or heart disease**
 - **take this product more frequently or take more than the recommended dose**
- avoid foods or beverages that contain caffeine
- avoid dietary supplements containing ingredients reported or claimed to have stimulant effect

Stop use and ask a doctor if

- your asthma is getting worse (see Asthma Alert)
- you have difficulty sleeping
- you have a rapid heart beat
- you have tremors, nervousness, or seizure
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than directed**
- adults and children 12 years and over: take 1 caplet every 4 hours as needed. Do not take more than 6 caplets in 24 hours or as directed by a doctor.
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

call **1-855-565-9800** weekdays 9 AM to 5 PM EST

Dist. by:

Foundation Consumer Healthcare, LLC.

Pittsburgh, PA 15205

PRINCIPAL DISPLAY PANEL - 24 Caplet Blister Pack Carton

NDC 69536-425-24

Ephedrine Sulfate/Bronchodilator

Guaifenesin/Expectorant

BRONKAID®

STRONGEST FORMULA

available in a **1** caplet dose

DUAL ACTION FORMULA:

- ▯ **Restores Free Breathing**
- ▯ **Loosens Phlegm**

Relief of Mild

Intermittent

Asthma Symptoms

PHARMACIST

RECOMMENDED

24

CAPLETS

Drug Facts (continued)

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CAPLETS

F.P.O. 85% UPC
TRUNCATED

DO NOT USE IF BLISTER
IS CUT OR BROKEN.

KEEP OUTER CARTON
FOR COMPLETE PRODUCT
INFORMATION

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Drug Facts (continued)

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- are not better in 60 minutes
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- need more than 6 caplets in 24 hours
- use more than 4 caplets in 24 hours for 3 or more days a week

Drug Facts (continued)

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- if you have ever had an allergic reaction to this product or any of its ingredients

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LEBG762D3



BRONKAID DUAL ACTION FORMULA

ephedrine sulfate and guaifenesin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69536-425
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPHEDRINE SULFATE (UNII: U6X61U5ZEG) (EPHEDRINE - UNII:GN83C131XS)	EPHEDRINE SULFATE	25 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

Inactive Ingredients

Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	BRONKAID
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69536-425-24	4 in 1 CARTON	01/01/2006	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2	NDC:69536-425-60	5 in 1 CARTON	01/01/2006	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part341	01/01/2006	

Labeler - Foundation Consumer Healthcare LLC (079675882)

Revised: 9/2016

Foundation Consumer Healthcare LLC